IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ALLERGAN SALES, LLC and ALLERGAN, INC. Plaintiffs, v. SANDOZ, INC. and ALCON LABORATORIES, INC. Defendants.	Civil Action No. 2:17-cv-10129 WHW-CLW ***Electronically Filed***

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS DEFENDANTS' INEQUITABLE CONDUCT AND ANTITRUST COUNTERCLAIMS AND TO STRIKE DEFENDANTS' TENTH AFFIRMATIVE DEFENSE, OR ALTERNATIVELY TO BIFURCATE AND STAY DEFENDANTS' ANTITRUST COUNTERCLAIMS

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I. INTRODUCTION

This Court should dismiss Sandoz's newly raised inequitable conduct and antitrust allegations.

As admitted in its pleading, Sandoz's voluminous inequitable conduct counterclaims relate to long ago events from the prosecution of patents that have already been litigated to finality by the parties. Paragraph 16 of Sandoz's Counterclaims, intended as an overview, makes the point that all of this long predates the current case and patents:

> The inequitable conduct set forth below pervades the entire Allergan Patent Family beginning with the first patent of this family, the '149 patent. The inequitable conduct occurring in the Allergan Patent Family patent applications has an immediate and necessary relationship to the issuance of the other patent applications. Moreover, the inequitable conduct occurring in the below referenced patent applications relates to the claimed subject matter of the other patent applications since the Allergan Patent Family patents all purport to claim a composition comprising timolol and brimonidine or its use in a method of reducing intraocular pressure (or treating glaucoma or ocular hypertension). Allergan also consistently represented throughout the prosecution of the Allergan Patent Family that the claimed compositions methods of treatment had unexpected results or surprising benefits when compared to other compositions, despite Allergan having contrary, material information that contradicted or refuted their arguments and representations for patentability. As such, the inequitable conduct committed in earlier applications infects and renders unenforceable the later applications in this patent family.

(Dkt. 73, Counterclaim ¶ 16.)

If any of the above were true—and four different court decisions have already ruled against Sandoz that none of it can possibly be so—the time to raise such allegations was in any of the two prior district court trials and two appeals on the merits between the parties over the "Allergan Patent Family." In those proceedings, which spanned 2009 through 2017, memories were far fresher, more witnesses were available, and courts could have considered the matters at the proper time without having to learn the subject matter anew.

But neither Sandoz nor Alcon[1] made any allegations in those prior cases concerning the massive conspiracy now alleged—namely, that every single person associated with the prosecution of the "Allergan Patent Family," from attorneys to scientists to secretaries, deliberately and willfully defrauded the United States Patent Office for a decade and a half. Sandoz would have this Court believe that this conspiracy went unnoticed by the legions of attorneys—including Sandoz's present counsel, who tried the last case between the parties—that have represented Sandoz for the past nine years, despite having access to every single fact and document about which they complain in these prior cases.

And while Sandoz may have no problem levying these career-altering allegations against twenty-one individuals at this late date, the law does. Having failed to raise these matters before, and having lost the prior cases on validity no fewer than four times, Sandoz is now barred from coming to this Court and asserting that otherwise valid patentable subject matter was somehow procured through fraud. Sandoz's allegations are neither permitted nor plausible, and its antitrust allegations stemming from are illogical: Allergan cannot have committed antitrust violations by having ***succeeded*** in enjoining Sandoz's proposed generic copy of Combigan® in contested, prior litigations as a matter of law.

Simply put, it is no small thing to accuse a single person of fraud, let alone 21 people years after the allegations might have been raised. Its assertions of inequitable conduct and antitrust violations should be seen for what they are—a final, desperate attempt to avoid Allergan's valid patent rights, based on unsupported allegations, in the hopes that their sheer

[1] Allergan generally refers to Sandoz and Alcon collectively as "Sandoz." Sandoz and Alcon were separately represented companies in the first litigation between the parties until Novartis, the parent of Sandoz, acquired Alcon in full in 2010.

volume will impress. The Court should respectfully dismiss them.

II. SUMMARY OF SANDOZ'S ALLEGATIONS[2]

A. The Patents-in-Suit and the "Allergan Patent Family" Claim Unexpected Results Achieved in the Clinical Trials for Allergan's Combigan® Product

Combigan® is a medication for lowering elevated intraocular pressure ("IOP"), the pressure of the fluid called aqueous humor inside the eye. (Dkt. 73, Counterclaim ¶¶ 18-19.)[3] While aqueous humor helps nourish the eye and maintain its shape, elevated IOP can harm the optic nerve, potentially leading to vision loss. (*Id.*) Patients with elevated IOP without detectable vision loss are diagnosed with "ocular hypertension"; those with detectable vision loss are diagnosed with glaucoma. (*Id.*) Combigan® is approved for lowering elevated IOP in both groups of patients. (*Id.*)

As its name suggests, Combigan® is combination drug product. (*Id.* ¶ 19.) Its two active ingredients are 0.2% brimonidine tartrate and 0.68% timolol maleate. (*Id.*) As may happen in a combination therapy, the individual drugs in the combination were first brought to market in the United States as monotherapies, as explained in Allergan's patents. (*Id.* ¶ 20.) 0.68% timolol

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[2] Obviously, space limits the extent to which a 150 page pleading containing vague and sweeping allegations can be summarized or addressed in a 40 page motion to dismiss. The court would be within its power to strike the entire pleading under Fed. R. Civ. P. 12(e) for this reason alone. *McHenry v. Renne*, 84 F.3d 1172, 1177-1178 (9th Cir. 1996).

[3] Unless otherwise noted, all citations are to Sandoz's answer, counterclaims, or any of the numerous documents, references and court filings cited therein. With respect to these other materials, given their citation by Sandoz, they are deemed integral to their counterclaims, and therefore proper for the Court to consider on a motion to dismiss. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). In addition, by citing the record of the prior litigations as a "sham," Sandoz has incorporated the public record of those litigations into their filing as well. *Id.* ("[W]hat is critical is whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited. . . . Plaintiffs cannot prevent a court from looking at the texts of the documents on which its claim is based by failing to attach or explicitly cite them.") (internal citations omitted). Although the materials cited here are all available in the record, Plaintiffs attach through the Declaration of Liza Walsh a small group of documents for ready access in the hope the Court will find that convenient.

maleate was first sold as Timoptic® by Merck, though it was commonly referred to as 0.5% timolol, in reference to the base component of timolol maleate known as timolol free base. (*Id.* ¶ 24.) Allergan first sold 0.2% brimonidine tartrate as Alphagan®. (*Id.* ¶ 21.) The FDA originally approved Timoptic® for twice a day administration in the United States, but only approved Alphagan® for three times a day administration. (*Id.* ¶¶ 21, 24.)

The FDA approved Combigan® in 2007, and Allergan began marketing the product thereafter. (Dkt. 73, Counterclaim ¶ 101.) Unlike Alphagan®, the FDA approved Combigan® for twice a day dosing in the United States. (*Id.* ¶ 31.)

Combigan® is covered by the three patents-in-suit, U.S. Patent Nos. 9,770,453 (the "'453 patent"), 9,907,801 (the "'801 patent"), and 9,907,802 (the "'802 patent). These patents all stem from a patent application that Allergan filed in 2002, the first patent from which issued in 2006, U.S. Patent No. 7,030,149 (the "'149 patent"). (*Id.* ¶¶ 32-33.) Claim 4 of the '149 patent, which Allergan and Sandoz have twice litigated to finality, claims a method of treating glaucoma or ocular hypertension patients, twice-a-day, with a composition comprising 0.2% "brimonidine" and 0.5% "timolol" that achieves certain therapeutic results in patients: namely, equivalent IOP-lowering compared to the prior, FDA approved, three times a day 0.2% brimonidine tartrate monotherapy Allergan sold as Alphagan®. (*Id.*, Answer ¶ 23; *id.*, Counterclaim ¶¶ 21, 166-167.)

In 2014, the Patent Office awarded Allergan U.S. Patent No. 8,748,425 (the "'425 patent"), also originating from the 2002 application. (Dkt. 73, Counterclaim ¶ 32.) Like the '149 patent, the '425 patent has also been litigated to finality by Allergan and Sandoz in this ongoing dispute, though only once. (*Id.* at Answer ¶ 28.) The '425 patent generally claims a method of treating glaucoma or ocular hypertension patients, twice a day, with a composition comprising 0.2% brimonidine tartrate and 0.5% timolol free base that also achieves particular

therapeutic results in patients—in this instance, reduction of one or more of seven adverse events compared to the prior, FDA approved, three times a day 0.2% brimonidine tartrate monotherapy. (*Id.* at Counterclaim ¶ 65.)

The three patents-in-suit claim the same subject matter as the '149 and '425 patents, with one important difference: the identity of the composition required by the claims. (*Id.* at Answer ¶ 32.) Whereas the already litigated '149 and '425 patents identify the composition as containing 0.2% brimonidine or brimonidine tartrate and 0.5% timolol or timolol free base, the three patents-in-suit all identify the composition as containing 0.2% brimonidine tartrate and 0.68% timolol maleate. (*Id.*) Other than this change, necessitated for reasons explained herein, the three patents-in-suit all cover a method of treating glaucoma or ocular hypertension patients that achieves one or both of the therapeutic results described above—i.e., equivalent efficacy to the FDA-approved three times a day 0.2% brimonidine tartrate monotherapy and/or reduced adverse events compared to that same therapy.

As detailed below, in the many prior years of litigation between the parties, with all their ups and downs, one thing has remained constant: courts have repeatedly found, despite strenuous argument from Sandoz, that the above-described (and claimed) therapeutic results achieved with Combigan® were "unexpected" or "surprising" results that demonstrated that Allergan's patents are not obvious over all the arguments Sandoz has ever raised. *See Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1293 (Fed. Cir. 2013) ("The court found that a twice per day dosage regimen of Combigan® unexpectedly did not suffer from the afternoon trough issue. We agree with the court's finding that this result is unexpected."); *id.* at 1294 ("Finally, the court found that there were secondary considerations that support the finding of non-obviousness including long-felt need and unexpected results. We accept the district court's factual findings

regarding the existence of these secondary factors[.]"); *Allergan Sales, LLC v. Sandoz, Inc.*, 717 F. App'x 991, 994 (Fed. Cir. 2017) ("Those efficacy limitations are not disclosed by any prior art reference in the record" and are "not inherent in the administration of the ophthalmic composition").

B. In Nine Prior Years of Litigation, Sandoz Never Challenged Allergan's Patents For Inequitable Conduct, and Lost Four Times in Its Efforts to Invalidate Allergan's Patents

Allergan first brought suit against Sandoz in 2009. After trial, the district court found that Sandoz infringed Allergan's claim 4 of the '149 patent (among others), and the claim was valid. (Dkt. 86-10, Walsh Decl., Ex. E). The Federal Circuit upheld that decision. *Allergan*, 726 F.3d at 1295. Sandoz then attempted to avoid that trial result by adjusting its label—a move the District Court called "less a design around [of] Allergan's patents and more a hypertechnical, if not illegal, end run around the injunction." (Dkt. 86-10, Walsh Decl., Ex. C, at 7.) Allergan again brought suit. And again after that second trial, the district court found that Allergan's patents were valid, and that Sandoz's proposed product infringed Allergan's '425 patent. (*Id.* at 12, 21.) On appeal, the Federal Circuit again upheld the district court's determination that Allergan's patents are valid. *Allergan Sales*, 717 F. App'x at 994. But on infringement, the Federal Circuit reversed, saying that Allergan had a "claiming problem" and would need to adjust the claim language. (Oral Arg. Rec. at 6:14, Nos. 17-1499 (Fed. Cir. Oct. 2, 2017) (available at http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017 1499.mp3.) The patents in this case fix that "claiming problem."

In all the time from that first case to this case—nine years—Sandoz has never alleged that Allergan's patents are unenforceable because of inequitable conduct. But now, facing patent claims with limitations that have been upheld four times, and patent claims that cure the "claiming problem," thus clearly covering Sandoz's product, Sandoz now, for the first time,

reaches for inequitable conduct.

1. 2009-2013: Litigation Over Sandoz's Traditional ANDA Copycat Product: the '149 Patent is Found Valid and Infringed After Trial and Appeal

In April 2009, after receiving Sandoz's notice of its intent to offer a generic copy of Allergan's Combigan®, Allergan sued Sandoz for infringement under the Hatch-Waxman Act. Allergan asserted four patents against Sandoz: the '149 patent, as well as U.S. Patent Nos. 7,320,976 (the "'976 patent"), 7,323,463 (the "'463 patent"), and 7,642,258 (the "'258 patent").

On the eve of trial, Sandoz stipulated to infringement of all of the asserted claims of the four patents-in-suit, including claim 4 of the '149 patent, leaving invalidity as its only defense. (Dkt. 86-10, Walsh Decl., Ex. B at 8:20-9:5; *id.*, Ex. D at 2.) After a four-day bench trial in August 2011, the district court found that Sandoz's generic version of Combigan® infringed the asserted claims and rejected all Sandoz's invalidity defenses. *Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d. 974, 977 (E.D. Tex. Aug. 22, 2011). As a result, the district court enjoined Sandoz from the manufacture, use, or sale of its copycat generic product, an injunction that remains in effect today. (Dkt. 86-10, Walsh Decl., Ex. E at 3-4.)

On appeal, the Federal Circuit affirmed the district court's judgment that claim 4 of the '149 patent is infringed and not invalid, thereby affirming the injunction. *Allergan*, 726 F.3d at 1288, 1295.[4] As noted above, the Court agreed with the district court's finding that the therapeutic results achieved with Combigan were unexpected. *Id.* at 1293-94. The Court also agreed that the prior art failed to disclose the efficacy limitation of claim 4, even over the prior art use of brimonidine and timolol twice per day. "[W]hile it is true that the prior art shows

[4] The Federal Circuit invalidated the '463 patent, which broadly claimed the combination of 0.2% brimonidine and 0.5% timolol without reciting the unexpected efficacy result. *Allergan*, 726 F.3d at 1293. Because it affirmed the '149 patent, the Federal Circuit declined to consider the district court's validity finding as to the '976 and '258 patents. *Id.* at 1294 n.2.

concomitant administration of brimonidine and timolol was dosed twice per day, this art ***does not show*** that there was no loss of efficacy associated with that treatment, let alone an elimination of the afternoon trough." *Id.* at 1294 (emphasis added).

Although the prosecution of the patents that were at issue in this litigation over Sandoz's original ANDA product, including the '149 patent, are the source of the majority of Sandoz's inequitable conduct allegations here, Sandoz did not raise inequitable conduct at trial in the case. Indeed, while Sandoz's answer stated summarily, with no detail, that "[t]he '149 patent and the '976 patent are unenforceable because Allergan has unclean hands," Sandoz never pursued the defense any further. (Dkt. 86-10, Walsh Decl., Ex. N at 10.) Instead, Sandoz was content to go to trial solely on the invalidity arguments that it ultimately lost.

2. 2014-2017: Litigation Over Sandoz's "Skinny Label" ANDA Product: the '149 and '425 Patents are Found Valid, But, Ultimately, Not Infringed on Appeal Because of a "Claiming Problem" in Allergan's Patents

After losing its effort to bring a traditional generic copy to market, Sandoz amended its ANDA in an attempt to avoid the first case's judgment. (*Id.*, Ex. A (*Allergan Sales*, slip op.) ¶ 33). As is sometimes permitted under the Hatch-Waxman Act, Sandoz changed its label from a copy of Combigan®'s label to what is sometimes called a "skinny label" that includes less than all the information on the Combigan® label. *GlaxoSmithKline LLC v. Glenmark Pharms. Inc.*, No. 14- CV-877-LPS-CJB, 2017 WL 8948973, at *2 (D. Del. May 23, 2017), report and recommendation adopted, No. 14-CV-877-LPS-CJB, 2017 WL 2536431 (D. Del. June 9, 2017). As noted above, Combigan® is approved to lower elevated IOP in both glaucoma and ocular hypertension patients. Sandoz's amendment deleted the words "glaucoma or," throughout the proposed package insert (Ex. A (*Allergan Sales*, slip op.) ¶ 34), thereby suggesting to the public

that its product was only to be used for ocular hypertension. This is the same product that is at issue in this case.

Based on this amendment, Sandoz sent Allergan the required notification about its amended ANDA.[5] Allergan then sued for infringement, and the parties began litigation over Sandoz's amended ANDA product under the Hatch-Waxman Act. All six of Allergan's then-existing Combigan® patents were at issue in the litigation, though by the time of trial, only three remained: the previously litigated '149 patent, the '425 patent, and a third patent from the first litigation, the '976 patent.[6] (*Id.* ¶¶ 38-39.)

At the three-day trial in October 2016, Sandoz's main argument at trial was again invalidity, asserting theories of obviousness, lack of written description, and non-enablement. (Ex. B, C.A. No. 2:12-cv-207, Dkt. 348, Sandoz's Nov. 10, 2016 FOF/COLs at 85-91.) On infringement, despite the prior judgment of infringement of the '149 and '976 patents as to Sandoz's traditional ANDA product, and despite the fact that it had made no change to the composition of its product, Sandoz argued that its skinny label ANDA product did not infringe any of the asserted claims because the product was made with 0.68% timolol maleate, and not

[5] Sandoz originally attempted to dispense with the procedures of the Hatch-Waxman Act, arguing that the Court should summarily consider its amendment in the context of a motion to amend the judgment from the first litigation over its traditional generic product under Fed. R. Civ. P. 60. (No. 2:09-CV-00097-TJW, (E.D. Tex.), Dkt. 285 at 1.) The district court rejected that effort, a decision that was affirmed on appeal. (No. 2:09-CV-00097-JRG, (E.D. Tex.), Dkt. 308 at 1); *Allergan, Inc. v. Sandoz, Inc.*, 587 F. App'x 657, 658 (Fed. Cir. 2014).

[6] While the appeal in the first litigation was pending, Allergan filed suit on Sandoz's original ANDA on two other patents, U.S. Patent Nos. 8,133,890 (the "'890 patent") and 8,354,409 (the "'409 patent") that, like the '425 patent, related to the reduced adverse events Combigan® provides patients. That case was stayed in December 2013, and eventually consolidated with the case regarding Sandoz's amended ANDA. Eventually, to streamline the trial, Allergan dismissed the'890, and '409 patents, as well as the '258 patent, from the case, and provided Sandoz with a covenant not to sue.

with 0.5% timolol or timolol free base. (*Id.* at 17-18.) What Sandoz did not do, however, is argue inequitable conduct at any time in the case, either at trial or before.

After trial, the district court rejected each of Sandoz's validity challenges, and expressly rejected Sandoz's challenges regarding the previously adjudicated unexpected results not actually being unexpected over the "closest prior art." According to the court: "the efficacy and side effect results of Combigan® are unexpected compared to ***all the prior art, including twice-daily adjunctive therapy***." (Ex. A (*Allergan Sales*, slip op.) at 61 (emphasis added).) On infringement, the district court found that Sandoz's product infringed the '425 patent, but did not infringe the '149 and '976 patents because Sandoz's product did not meet the limitations of those patents requiring 0.2% "brimonidine" and 0.5% "timolol." (*Id.* at 18-21.) Notably, despite Sandoz's skinny label to only ocular hypertension patients, the district court found that Sandoz intended to sell its product to glaucoma patients as well. (*Id.* at 34-36.)

On appeal, the Federal Circuit affirmed all the district court's findings on validity of all three patents. *Allergan Sales*, 717 F. App'x at 992. As noted above, with respect to the unexpected results of equivalent efficacy and reduced adverse events, the Federal Circuit was emphatic that those limitations, which it grouped together as "efficacy limitations," were not obvious over the prior art. *Id.* at 994.

On infringement, however, the Federal Circuit found that Sandoz's product did not infringe any of the claims because Sandoz's product was made with 0.68% timolol maleate and not 0.5% timolol free base. *Id.* at 995-96. At argument on the appeal, one judge on the reviewing panel diminished this issue as a "claiming problem," as opposed to some fatal flaw in Allergan's patents.

C. The Present Litigation—Sandoz Prepares to Launch its "Skinny Label" ANDA Product Despite the Patent Office Allowing Allergan to Fix the "Claiming Problem" With the Patents-in-Suit

In light of the district court's acceptance of Sandoz's arguments about the "claiming problem" in at least some of Allergan's Combigan® patents, Allergan applied for new patents covering Combigan® that fixed this issue. Between September 2017 and March 2018, the PTO allowed and issued the patents-in-suit. As noted above, these patents incorporate the therapeutic results that have been repeatedly ruled unexpected, while fixing the so-called "claiming problem" from the prior patents.

Allergan filed its original complaint in this case on October 30, 2017, asserting the '453 patent. (Dkt. 1.) Sandoz answered on December 19, 2017, but did not assert antitrust or inequitable conduct counterclaims. (Dkt. 18.) After the '801 and '802 patents issued earlier this year, Allergan amended its complaint by agreement to add them to the dispute. (Dkt. 66.) The parties then negotiated a case schedule that would allow for an early preliminary injunction hearing, as well as a fast overall resolution of the case, respecting both parties' desire to bring this dispute to a final close. (Dkt. 34.) At no time during this process did Sandoz inform Allergan (or the Court) that it intended to file a 150-page inequitable conduct and antitrust counterclaim.

Then, just days before Allergan's preliminary injunction motion was due, on April 17, 2018, Sandoz filed its amended answer and counterclaims with over 400 paragraphs of allegations related to asserted inequitable conduct, antitrust violations and so-called "sham litigation." (Dkt. 73.)

D. Sandoz Now Alleges a Conspiracy Involving Over 20 People and Spanning Over a Decade, Beginning 16 Years Ago

Sandoz now concocts a sprawling conspiracy of inequitable conduct, done by twenty-one people, spanning over a decade, stretching back at least sixteen years to 2002, and involving thirty overt acts. And while Sandoz never made this accusation in nine years of prior litigation, the documents it cites in support of its theory have already been considered by the courts in the prior litigations, and the arguments underpinning the accusation have been rejected by the Eastern District of Texas twice, and by the Federal Circuit, twice.

The sweeping scope of Sandoz's allegations defies plausibility. In 150 pages, Sandoz accuses every prosecutor mentioned in the file histories—eight attorneys/patent agents. Sandoz accuses every inventor—four inventors. Sandoz accuses every person who submitted a declaration in support of patentability—three declarants. Sandoz even includes every secretary or assistant whose name appears in the file history—six staff employees. And those twenty-one people supposedly committed thirty acts of dishonesty with the specific intent to deceive the Patent Office. And this pattern of intentional dishonesty supposedly took place from 2002 to 2011, with yet another alleged act of misconduct in 2016.

We have struggled to try to summarize in the confines of this brief what Sandoz now claims to see. The gravamen of the allegations follows in the chart below. We set out for the Court not only the charge, but also when the supposed bad conduct first occurred to show the Court that Sandoz could have, and should have, raised this claim years ago.

(1) failure to inform the Patent Office as to the closest prior art **(listing 4 bad acts, ¶¶ 185-192 of Counterclaims)**	**Case in Which Sandoz Could and Should Have First Raised Claim**	**Year that Alleged Bad Act First Occurred**
• Representation by Brent Johnson (¶ 186)	First Litigation	2004
• Representation by Brent Johnson (¶ 187)	First Litigation	2005
• Representation by John Wurst (¶ 190)	Second Litigation	2011

• Failure to disclose the David reference (¶¶ 188, 190)	First Litigation	2004
(2) misrepresentations about central nervous system side effects **(listing 9 bad acts, ¶¶ 211-225 of Counterclaims)**	**Case in Which Sandoz Could and Should Have First Raised Claim**	**Year that Alleged Bad Act First Occurred**
• Declaration by Dr. Schiffman (¶¶ 212, 214)	First Litigation	2004
• Submission by Brent Johnson (¶ 213)	First Litigation	2004
• Representation made by Brent Johnson about Goni (¶¶ 218-221)	First Litigation	2005
• Failure to submit the -507T trial (¶ 222)	First Litigation	2004-2005
• Failure to tell PTO of FDA review of 19T study (¶ 215)	First Litigation	2005
• Failure to identify Dr. Schiffman as an employee (¶¶ 216-217)	First Litigation	2004
• Additional submissions of Schiffman declaration on IDSes, with no correction (¶ 217)	Second Litigation	2007
• Failure to disclose the Combigan Medical Review (¶ 223)	First Litigation	2004-2005
• Failure to disclose the Alphagan Final Report (¶224)	First Litigation	2004-2005
(3) failure to tell PTO of data in litigation expert report **(listing 1 bad act, ¶ 250 of Counterclaims)**	**Case in Which Sandoz Could and Should Have Raised Claim**	**Year that Alleged Bad Act First Occurred**
• Failure to disclose Dr. Duh expert report or data therein re ocular hypertension (¶ 250)	Second Litigation	2016
(4) false and misleading statements about unexpected results on somnolence **(listing 5 bad acts, ¶¶ 266-272 of Counterclaims)**	**Case in Which Sandoz Could and Should Have First Raised Claim**	**Year that Alleged Bad Act First Occurred**
• Argument by John Wurst (¶ 267)	Second Litigation	2011
• Submission by John Wurst in 2011 about -023T trial (¶¶ 268-269)	Second Litigation	2011

• Failure to submit FDA Medical Review (¶¶ 270-271)	Second Litigation	2011
• Failure to disclose clinical data (Goni, David, -507T trial) (¶ 267)	Second Litigation	2007
• Failure to disclose Alphagan Final Report (¶ 272)	Second Litigation	2007
(5) false and misleading statements that Combigan® was as effective as brimonidine TID/timolol BID therapy **(listing 4 bad acts, ¶¶ 292-295 of Counterclaims)**	**Case in Which Sandoz Could and Should Have First Raised Claim**	**Year that Alleged Bad Act First Occurred**
• Submission by Robert Baran (¶ 293)	First Litigation	2005
• Submission by Brent Johnson (¶ 293)	First Litigation	2005
• Submission by Brent Johnson (¶ 294)	First Litigation	2005
• Failure to tell PTO about FDA analysis of 19T data (¶ 295)	First Litigation	2005
(6) withholding Alphagan Final Report, Clinical Trials, and David reference **(listing 2 bad acts, ¶¶ 307-314 of Counterclaims)**	**Case in Which Sandoz Could and Should Have First Raised Claim**	**Year that Alleged Bad Act First Occurred**
• Failure to disclose 12T trial, 13T trial, Alphagan Final Report (¶ 309)	Second Litigation	2011
• Failure to submit David reference (¶¶ 310-314)	First Litigation	2002
(7) withholding less favorable clinical data before 2002 filing date of '149 patent **(listing 2 bad acts, ¶¶ 331-334 of Counterclaims)**	**Case in Which Sandoz Could and Should Have Raised Claim**	**Year that Alleged Bad Act First Occurred**
• Failure to submit 12T trial (¶¶ 331-334)	First Litigation	2002
• Failure to disclose data found in Alphagan® Final Report (¶ 333)	First Litigation	2002

(8) a pattern of burying or concealing information in IDSs **(listing 3 bad acts, ¶¶ 352-355 of counterclaims)**	**Case in Which Sandoz Could and Should Have Raised Claim**	**Year that Alleged Bad Act First Occurred**
• Submission of hundreds of references throughout prosecution (¶ 352)	Second Litigation	2010
• Improperly submitting the Combigan® Medical Review (¶¶ 353-354)	Second Litigation	2010-2011
• Burying Combigan® Medical Review (¶ 355)	Second Litigation	2012

Tellingly, no firm that has represented Sandoz—not Duane Morris, not Rakoczy Molino, not Morrison & Foerster, and not Kirkland & Ellis (retained in 2016)—in nine years of litigation, pouring over seven hundred thousand pages, deposing witnesses for dozens and dozens of hours, and trying the case twice—ever made these accusations of inequitable conduct, which are based on the identical record from the prior cases. Inventor Amy Batoosingh's story alone makes the point. Ms. Batoosingh, a Senior Director of Clinical Development, who managed the clinical trials for Combigan®, has been deposed over five days for more than twenty-seven hours (there have been 67 depositions so far) and testified at trial twice. And yet Sandoz failed to make these accusations of inequitable conduct.

As detailed below, Sandoz's counterclaims fail strict standards of pleadings set out by the Federal Circuit, the Third Circuit, and the Supreme Court. To be successful, they would require ignoring prior rulings of the Federal Circuit, and disregarding nine years of litigation between the parties. The Court should dismiss Sandoz's counterclaims forthwith.

III. LEGAL STANDARDS

A counterclaim may be dismissed[7] for "failure to state a claim upon which relief can be

[7] Sandoz also raises inequitable conduct as an affirmative defense, simply incorporating by reference the allegations made in its counterclaims. (Dkt. 73, Defenses ¶¶ 12-14.) Sandoz's

granted." Fed. R. Civ. P. 12(b)(6).[8] The legal sufficiency of a counterclaim accusing nearly two dozen people of a nearly two decade long conspiracy to perpetrate a fraud on the Patent Office and the courts faces a number of pleading hurdles, and rightly so.

Because Sandoz alleges "infectious inequitable conduct" going back to the previously litigated '149 patent, Sandoz is barred by the doctrine of claim preclusion for failing to bring a compulsory counterclaim in earlier litigation over Combigan®. A counterclaim is compulsory if it "arises out of the transaction or occurrence that is the subject matter of the opposing party's claim . . ." Fed. R. Civ. P. 13(a)(1). "For a claim to qualify as a compulsory counterclaim, there need not be precise identity of issues and facts between the claim and the counterclaim; rather, the relevant inquiry is whether the counterclaim bears 'a logical relationship to an opposing party's claim.'" *Transamerica Occidental Life Ins. Co. v. Aviation Office of Am., Inc.*, 292 F.3d 384, 389–90 (3d Cir. 2002). "A counterclaim which is compulsory but is not brought is thereafter barred." *Baker v. Gold Seal Liquors, Inc.* 417 U.S. 467, 469, n.1 (1974). The doctrine of claim preclusion in turn "gives dispositive effect to a prior judgment if a particular issue, although not litigated, could have been raised in the earlier proceeding." *Blunt v. Lower Merion Sch. Dist.*, 767 F.3d. 247, 276 (3d Cir. 2014). [9]

Next, in alleging "fraud or mistake, a party must state with particularity the

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affirmative defenses thus fail for the same reasons as its counterclaims, and Allergan respectfully requests that the Court strike affirmative defense number 10. *See Taro Pharms. N. Am., Inc. v. Suven Life Sci., Ltd.*, No. 11- CV-2452 (JAP), 2012 WL 2513523, at *3-6, 7 (D.N.J. June 28, 2012) (granting motion to dismiss inequitable conduct counterclaims and strike affirmative defenses based on same analysis).

[8] Third Circuit law governs the procedural aspects of this motion. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1318 (Fed. Cir. 2009). Substantive patent issues are controlled by Federal Circuit decisions. *Golan v. Pingel Enter., Inc.*, 310 F.3d 1360, 1368 (Fed. Cir. 2002).

[9] Regional circuit law governs the standard for claim preclusion. *Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1323 (Fed. Cir. 2008).

circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). But it is not enough simply to file a very long pleading—the allegations must be plausible. "Determining whether a complaint states a plausible claim for relief [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. . . . But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not "show[n]"—"that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) (internal citations omitted).

Here, the charge is inequitable conduct, an accusation which "focuses on the moral turpitude of the patentee with ruinous consequences for the reputation of his patent attorney" and as such "has plagued not only the courts but also the entire patent system." *Therasense, Inc. v. Becton Dickinson and Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (en banc). The law thus demands that Sandoz's counterclaim plausibly allege that "specific intent to deceive [is] 'the single most reasonable inference able to be drawn'" from Sandoz's characterizations about the actions of the twenty or more persons accused. *Id.* at 1290; *see also Mycone Dental Supply Co., Inc. v. Creative Nail Design, Inc., et al.*, No. 11-CV-4380, 2013 WL 3216145, at *4-5 (D.N.J. June 24, 2013). This specific intent is a high standard; "it is not enough to argue carelessness, lack of attention, poor docketing or cross-referencing, or anything else that might be considered negligent or even grossly negligent." *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1375-76 (Fed. Cir. 2012). Moreover, Sandoz must plausibly show that the information it claims was concealed was material—that is, "but for" its concealment, the patents would never have issued. *Therasense*, 649 F.3d at 1296. And Sandoz's inequitable conduct claims are a necessary—although not sufficient—predicate to finding *Walker Process* fraud. *See id*. at 1289.

Finally, Sandoz's counterclaims alleging antitrust liability based on sham litigation face an equally demanding standard. Allergan is free to enforce its patent rights unless that enforcement is "objectively baseless." *Prof'l Real Estate Inv's, Inc., v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993). That is particularly true where, as here, the litigant enforcing its rights has prevailed. "A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." *Id.* at 60 n.5.

IV. ARGUMENT

A. Sandoz's Inequitable Conduct and *Walker Process* Counterclaims (Counterclaims 7-15) Fail Because They Are Compulsory Counterclaims Not Raised in Prior Related Litigation

Sandoz's counterclaims should be dismissed for the simple reason that they are based on compulsory counterclaims from the previous litigations between Allergan and Sandoz that Sandoz failed to raise. By Sandoz's own admission, its inequitable conduct allegations ***do not*** relate to conduct occurring during prosecution of the patents-in-suit. Instead, Sandoz alleges that "the inequitable conduct ***committed in earlier applications*** infects and renders unenforceable the later application in this patent family." (Dkt. 73, Counterclaim ¶ 16 (emphasis added).) While the patents-in-suit here were not part of the earlier litigations, the earlier patents on which Sandoz's inequitable conduct allegations rest were. Before Sandoz lost multiple times on validity, it never (although it plainly could have) sought to employ "the 'atomic bomb' of patent law." *Therasense*, 649 F.3d at 1288. Sandoz's attempt to belatedly assert these inequitable conduct claims now, nine years after the start of litigation on this family, is barred by Fed. R. Civ. P. 13(a) and the doctrine of claim preclusion.

The technical theory on which Sandoz relies is known as the doctrine of "infectious" inequitable conduct. (*See, e.g.*, Dkt 73, Counterclaim ¶¶ 16, 183, Thirteenth Counterclaim.) This doctrine is based on acts that occurred in the prosecution of earlier patents in a patent family

in rare circumstances. *Mosaid Techs. Inc. v. Samsung Elecs. Co.*, 362 F. Supp. 2d 526, 553-54 (D.N.J. 2005); *see also Eaton Corp. v. Parker-Hannifin Corp.*, No. 00-CV-751-SLR, 2003 WL 179992, at *1 (D. Del. Jan. 24, 2003) ("Inequitable conduct charges are disfavored . . . and charges of 'infectious inequitable conduct' even more so."); *Therasense*, 649 F.3d at 1288-89. Hence, "[t]o prove infectious unenforceability, an accused infringer must establish two elements: (1) that a patent is unenforceable due to inequitable conduct; and (2) that related patents bear an immediate and necessary relation to that alleged inequitable conduct." *Mosaid Techs. Inc.*, 362 F. Supp. 2d 553-54. Thus, under the very theory that Sandoz relies on, it must show inequitable conduct of the patents that were already litigated in the earlier suits.

As such, Sandoz's counterclaims of inequitable conduct and *Walker Process* violations require proof of compulsory counterclaims from the parties' prior litigations. Courts in this Circuit have held routinely that claims of inequitable conduct and *Walker Process* fraud arising out of an opposing patent infringement action—as Sandoz's do here—satisfy Rule 13(a)'s logical relationship test. *See Goodman Mfg. Co., LP v. Carrier Corp.*, No. 13-2014-SLR, 2014 WL 4954281, at *1-2 (D. Del. Sep. 23, 2014) (concluding claims of inequitable conduct were compulsory counterclaims to patentee's previously-filed and answered infringement claims because both involve "fundamental issues of patent law," based on the same facts); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928, 931, 933-35 (D. Del. 1991) ("[T]he fraudulent procurement of a patent claim, whether asserted as a defense to an infringement suit or brought separately as an antitrust claim is 'logically related' to a claim for patent infringement" because

"claims of fraud on the PTO directly implicate issues of patent law, and stem from the same 'roots' as infringement claims").[10]

Sandoz's inequitable conduct allegations plainly have a "logical relationship" to Allergan's prior claims of patent infringement on other patents in the Combigan® patent family. Indeed, that is part of what Sandoz must show to prevail on its theory of "infectious" inequitable conduct. *See Mosaid Techs.*, 362 F. Supp. 2d at 553-54 (discussing "immediate and necessary relationship" standard between earlier patent and subsequent patent required to show infectious unenforceability). In the first litigation over Sandoz's full labeled generic copy, Allergan brought claims for patent infringement of the '149, '976, '463, and '258 patents, and in the second litigation over Sandoz's skinny labeled product, Allergan brought infringement allegations on the '149, '976, '258, '890, '409, and '425 patents. Sandoz's allegations here expressly relate to supposed "misconduct" that occurred not during the prosecution of the patents-in-suit, but during the prosecution of the previously-litigated '149, '463, '890, and '409 patents. (*See supra* Section II.)

And yet, before the amended answer that Sandoz filed on April 17, 2018, Sandoz has never pursued inequitable conduct defenses or counterclaims or asserted *Walker Process* violations against these patents in any of the prior litigations. Sandoz should be barred from bringing these claims now. *See, e.g., Baker v. Gold Seal Liquors, Inc.*, 417 U.S. 467, 469 n.1 (1974) ("A counterclaim which is compulsory but is not brought is thereafter barred." (internal

[10] For many of the same reasons, Third Circuit district courts have ruled that *Walker Process* claims are also compulsory counterclaims to patent infringement suits. *See, e.g., Am. Packaging Corp. v. Golden Valley Microwave Foods, Inc.*, Civ. A. No. 94- CV-1839, 1995 WL 262522, at *3-6 (E.D. Pa. May 1, 1995) ("Thus, I find the case law holding Walker Process claims to be compulsory counterclaims is controlling.")

citation omitted)).[11] This result attaches either under Rule 13(a) or principles of claim preclusion (i.e., *res judicata*). *See Cyclops Corp. v. Fischbach & Moore, Inc.*, 71 F.R.D. 616, 620 (W.D. Pa. 1976). "Therefore, since a compulsory counterclaim is an issue that should have been raised, *res judicata* demands that counterclaims not pleaded cannot be the subject of separate, subsequent suits." *Id.* at 621.

Sandoz's belated attempt to litigate claims that relate to the patents already litigated to final judgement—after 10 additional years of faded memories and failing health of at least one of the accused attorneys—is precisely the type of situation Rule 13 sought to avoid. As the Supreme Court has noted, "[t]he Rule was particularly directed against one who failed to assert a counterclaim in one action and then instituted a second action in which the counterclaim became the basis of the complaint." *Southern Construction Co., Inc. v. Pickard*, 371 U.S. 57, 60 (1962); *Polymer Indus. Prod. Co. v. Bridgestone/Firestone, Inc.*, 347 F.3d 935, 939 (Fed. Cir. 2003). Simply put, Sandoz's unexcused failure to bring compulsory counterclaims of inequitable conduct in earlier litigations precludes it from doing so now. *See id.*; *see Goodman Mfg.*, 2014 WL 4954281, at *1-2 (dismissing inequitable conduct claims in later-filed declaratory judgment action as "forever barred" because they were compulsory counterclaims in earlier patent infringement action); *Am. Packaging Corp.*, 1995 WL 262522, at *4 (granting summary judgment that antitrust claims based on inequitable conduct were compulsory counterclaims in

[11] *See also Polymer Indus. Prod. Co. v. Bridgestone/Firestone, Inc.*, 347 F.3d 935, 938 (Fed. Cir. 2003) ("[A] party that does not assert its compulsory counterclaim in the first proceeding has waived its right to bring the counterclaim and is forever barred from asserting that claim in future litigation."); *NLRB v. Dutch Boy, Inc.*, 606 F.2d 929, 932 (10th Cir. 1979) ("The inherent character of a compulsory counterclaim . . . is that it is the type of claim which must be raised before the current tribunal or be forever lost to the claimant."); *Loader Leasing Corp. v. Kearns*, 83 F.R.D. 202, 203–04 (W.D. Pa. 1979) ("The failure to assert a compulsory counterclaim is a bar to a subsequent action in either a federal or state court.").

earlier patent litigation, and thus barred); *Rohm & Haas*, 770 F. Supp. at 931-32, 934-35 (precluding antitrust and fraudulent patent procurement actions that should have been brought as compulsory counterclaims to patent infringement action).[12]

B. Counterclaims 7-15 Should be Dismissed Because Sandoz's Allegations Fail Both the Therasense Requirements for Materiality and Intent and the *Iqbal/Twombly* Requirement for Plausibility

In addition to being precluded, Sandoz's allegations also fail to meet either the strict but-for materiality and intent requirements set by the Federal Circuit in *Therasense,* or the plausibility standard of *Iqbal* and *Twombly*. Sandoz's inequitable conduct allegations here are exactly the kind of allegations that the Federal Circuit called in *Therasense* a "plague" on the patent system that the Court was attempting to end, and that the Supreme Court held in *Iqbal* did not, without plausible allegations, warrant further litigation past the pleading stage. *Therasense,* 649 F.3d at 1289; *Iqbal*, 556 U.S. 662 at 687.

1. Sandoz's Allegations Lack "But For" Materiality and Intent Because Courts Have Repeatedly Found the Therapeutic Claim Limitations Were Unexpected Results (All Bases, Counterclaims 7-18)

Four federal courts—the Eastern District of Texas on two occasions, and the Federal Circuit on two occasions—have found that the therapeutic results that are also claimed in the patents-in-suit were unexpected, supporting the patentability of the claims. *Allergan*, 818 F. Supp. 2d. at 999; *Allergan*, 726 F.3d at 1293-94; Ex. A (*Allergan Sales*, slip op.) at 24-30;

[12] Sandoz's *Walker Process* claims alleging conduct related to patents '149, '463, '425, and '890 are also time-barred. The Clayton Act has a four year statute of limitations. 15 U.S.C. § 15b. And "[f]or antitrust actions involving patent fraud, the four-year statute of limitations generally begins running when the allegedly fraudulently procured patent is issued." *Westlake Servs., LLC v. Credit Acceptance Corp.*, 2017 WL 8948263, at *3 (C.D. Cal. Dec. 28, 2017). At a minimum, four of Sandoz's bases for alleged inequitable conduct (1, 4, 5, and 8) involve patents whose limitations periods have long since expired ('149 expired in 2010; '463 expired in 2014; '890 expired in 2015; and '425 expired April 7, 2017). Sandoz cannot save these claims simply by alleging "infectious inequitable conduct" for a host of patents citing conduct occurring over a decade ago.

Allergan Sales, 717 F. App'x at 994. And those findings were made in the face of extensive argument by Sandoz, and two separate full trial records. Sandoz has therefore litigated the unexpected results issue repeatedly, and lost. The unexpected results issue is precisely the same for the patents-in-suit, which recite the same therapeutic limitations already found multiple times to be unexpected. (Dkt. 1-1, Ex. A; Dkt. 57-1, Walsh Decl., Ex. KK) ('453 and '801 patents—adverse events); Dkt.1-1, Ex. A; Dkt. 57-1, Walsh Decl., Ex. LL ('453 and '802 patents—efficacy).) Accordingly, issue preclusion should bar Sandoz from challenging unexpected results yet again here. *See In re Freeman*, 30 F.3d 1459, 1469 (Fed. Cir. 1994); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l., Inc.*, 763 F. Supp. 2d 671, 676-77 (D. Del. 2010) (finding defendant estopped from asserting obviousness of a claim where obviousness of different claim containing same limitation was litigated in prior suit); *Bourns, Inc. v. U.S.*, 537 F.2d 486, 492 (Ct. Cl. 1976) (precluding relitigation of different patent claim where "patentee has once been heard on all the factual issues necessary to an obviousness determination").

But even beyond issue preclusion, the court findings of unexpected results in prior cases show that Sandoz's allegations cannot meet the materiality or intent requirements of *Therasense* as a matter of law. All eight of Sandoz's bases for inequitable conduct rely on the argument that, if the Examiner had known about a particular piece of data or prior art, he or she would not have found that the claimed invention demonstrated unexpected results, and thus would not have allowed the claims. Sandoz's allegations admit the dependence of each basis on the allegedly material information showing an alleged lack of unexpected results:

- Basis 1: Sandoz alleges that Allergan's closest prior art argument to the Examiner was a "material misrepresentation/omission because identification of the closest prior art was used by the Examiners … to evaluate claims of **unexpected results**." (Dkt. 73, Counterclaim ¶ 186 (emphasis added).)
- Basis 2: Sandoz alleges that, if Allergan had not "mischaracterized" certain clinical results "as showing that the claimed treatment method resulted in fewer CNS adverse

events, the Examiners would have rejected the claims because the claimed treatment methods did not show **unexpected results**." (*Id.* ¶ 239 (emphasis added).)

- Basis 3: Sandoz alleges that Allergan withheld "material data…showing that Combigan® is not as effective as brimonidine TID at all time-points," which is "highly material" and "reads directly on Allergan's representations regarding alleged **unexpected results**…." (*Id.* ¶ 250 (emphasis added).)
- Basis 4: Sandoz alleges that if Allergan had called "material information" about the clinical trials to the Examiner's attention, "the Examiner would have rejected the claimed treatment methods because the claimed treatment did not show **unexpected results** as to at least the incidence of the adverse event of somnolence." (*Id.* ¶ 288 (emphasis added).)
- Basis 5: Sandoz alleges that if Allergan had provided the Examiner with information supposedly showing that Combigan® is not as effective as brimonidine TID/timolol BID, "the Examiner would have rejected these claims at least because they provided no **unexpected results** … with respect to the full scope of the claimed subject matter." (*Id.* ¶ 303 (emphasis added).)
- Basis 6: Sandoz alleges that if Allergan had provided the Examiner with additional art, "the Examiner would have been apprised that any … **unexpected results** would not have been commensurate with the full scope of the claims" and this "material information" would "have rebutted an argument made for patentability made by Allergan." (*Id.* ¶ 325 (emphasis added).)
- Basis 7: Sandoz alleges that "throughout prosecution of the Allergan Patent Family member patents, Allergan repeatedly represented that the claimed composition/method of treatment using brimonidine/timolol BID in a single composition provided **unexpected results with regard to safety and efficacy,**" and that, "[h]ad the Examiner been presented with the material information relating to the -012T, -013T trial and Alphagan Final Report … the Examiner would have appreciated that Allergan's **claims regarding safety and efficacy** were at best overstated, if not plainly false." (*Id.* ¶¶ 345-346 (emphasis added).)
- Basis 8: Sandoz alleges that if the Examiner had been aware of all the relevant information in the references, "the Examiner would have appreciated that Allergan's representations respecting **unexpected benefits or properties of Combigan® were at best overstated, if not entirely false**" and "would have rejected the claims of the Allergan Patent Family members." (*Id.* ¶ 365 (emphasis added).)

In order to show materiality, Sandoz must be able to demonstrate that "because of the misrepresentation or omission, the patent at issue is not patentable." *See Eagle View Tech., Inc. v. Xactware Solutions, Inc.*, No. 15-CV-07025 (RBK/JS), 2018 WL 1522708, at *8 (D.N.J. Mar. 28, 2018) (granting "plaintiffs' motion under Rule 12(b)(6) to dismiss defendants' inequitable conduct claim"). The documents, testimony, and file histories on which Sandoz relies are not

new information, but are all part of the record of the prior proceedings, as is readily ascertainable from the public records of those proceedings. And not only was that record presented, Sandoz vigorously argued that there were no unexpected results based on that record. In the face of that record, each of Judges Ward and Gilstrap confirmed that therapeutic results achieved with Combigan® and claimed in the patents-in-suit were unexpected, and that Allergan's similarly worded claims were valid. (Ex. A (*Allergan Sales*, slip op.) ¶¶ 105, 162-165; Ex. C, *Allergan, Inc. v. Sandoz Inc.*, No. 2:09-cv-097, slip op. at ¶¶ 138-146 (E.D. Tex. Aug. 22, 2011).) And two separate panels of the Federal Circuit affirmed those findings. *Allergan*, 726 F.3d at 1293-94; *Allergan Sales*, 717 F. App'x at 994.

The findings in these prior decisions destroy both the requisite "but for" requirement and the plausibility of Sandoz's allegations here. Because two district courts and two panels of the Federal Circuit have found that Combigan® exhibits unexpected safety and efficacy in the face of all of the evidence that Allergan allegedly withheld from the PTO, Sandoz cannot establish that evidence was but-for material to patentability, nor is it plausible to plead that there is such materiality. *See, e.g.*, *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (affirming dismissal of inequitable conduct counterclaim where alleged prior art would not render asserted claims obvious in light of other cited prior art as a matter of law, and was therefore not material).

Similarly, far from being the "single most reasonable inference," as required by *Therasense*, it is completely unreasonable to infer that any of the myriad individuals acted with the intent to deceive the examiner by making arguments and taking positions with which the courts have agreed. A finding of specific intent requires that Sandoz plausibly demonstrate that "the applicant knew of [a] reference, knew it was material, and made a deliberate decision to

withhold it." *Therasense*, 649 F.3d at 1290. None of Sandoz's allegations can plausibly meet this standard. Simply put, Sandoz's disagreement with the findings of courts based on the same record that has already been considered cannot, as a matter of law, form the basis for an allegation that any individual—let alone 21 attorneys, inventors, scientists, and secretaries—acted in a mass conspiracy to deceive the Patent Office. The counterclaims should be dismissed.

2. Considered Individually, Each of Sandoz's Eight "Bases" Fail for Additional Reasons

a. Sandoz's Allegations Regarding the "Closest Prior Art" Are Not Plausible Because Attorney Argument Can Not Be a Material Misrepresentation as a Matter of Law (Basis 1)

Sandoz alleges that Allergan's arguments to the PTO during the prosecution of the '149 patent—the very first patent in the family—regarding the "closest prior art" constitute a material misrepresentation and/or omission. (Dkt. 73, Counterclaim ¶ 185.) To be clear, Sandoz does not allege, because it cannot, that Allergan hid the closest prior art from the PTO. Indeed, Allergan directly addressed Sandoz's alleged "closest prior art"—twice daily serial therapy with brimonidine and timolol—with the Examiner. (*Id.*; Ex. D, '149 File History, Aug. 24, 2005 Reply at 5 ("Applicants believe that this treatment regimen is not the closest prior art regimen because, as explained above, the person of ordinary skill in the art in this country is likely to follow the FDA recommended thrice a day dosing for brimonidine.").) Instead, Sandoz faults the advocacy of Allergan's prosecuting attorneys in arguing to the Examiner that twice-daily serial therapy was not the closest prior art because a skilled artisan would use the FDA-approved regimen including brimonidine dosed three times daily. (Dkt. 73, Counterclaim ¶ 185; Ex. D, '149 File History, Aug. 23, 2005 Reply at 4.)

Both the Federal Circuit and this district have held that attorney arguments on the interpretation of references are not material misrepresentations of fact. In *Young v. Lumenis*,

Inc., the Court rejected an inequitable conduct allegation based on advocacy at the Patent Office, finding that where the Examiner had the reference and was "free to reach his own conclusions and accept or reject Young's arguments" that "attorney argument and an interpretation of what the prior art discloses" could not constitute affirmative misrepresentations of material fact. 492 F.3d 1336, 1349 (Fed. Cir. 2007). This district is no different. In *Artemi Ltd. v. Safe-Strap Co.*, this Court dismissed a defendant's inequitable conduct claims where the alleged "misrepresentations" were not misrepresentations of fact, but instead were attorney "interpretations of meaning." No. 03-CV-3382 (JEI/AMD), 2013 WL 6860734, at *4 (D.N.J. Dec. 20, 2013). The court explained that "[a]dvocating for a particular understanding of a claim's language during reexamination and reissue does not violate an applicant's duty of candor to the USPTO." *Id.*

The same is true here—the issue of what art qualifies as the "closest prior art" is not a question of fact, but instead, is a matter of advocacy and legal argument. Advocacy for a particular understanding of the closest prior art cannot be a material misrepresentation ***of fact*** and thus cannot constitute inequitable conduct. *See Young*, 492 F.3d at 1349. And Allergan's legal argument as to the closest prior art cannot plausibly be unreasonable or misleading when the district court in the 2009-2013 litigation expressly agreed with it:

> Allergan's analysis of unexpected results compares the results of the claimed invention with treatment regimens that are set out in the claims themselves (e.g., TID brimonidine versus the fixed combination, as in Claim 4 of the '149 patent) and treatment regimens (e.g., brimonidine monotherapy) that were undertaken to secure FDA approval of Combigan®. ***The comparisons made by Allergan are appropriate.***

Allergan, 818 F. Supp. 2d at 1024 (emphasis added).

Moreover, the district court in the 2014-2017 litigation specifically considered and rejected Sandoz's closest prior art argument, ultimately determining that "the efficacy and side

effect results of Combigan® are ***unexpected compared to all prior art, including twice-daily adjunctive therapy***, based properly on what was knowable through such prior art," and the Federal Circuit affirmed that finding. (Ex. A (*Allergan Sales*, slip op.) at ¶¶ 166-67 (emphasis added).) And because the results have been found unexpected against ***all*** prior art, including Sandoz's alleged "closest prior art," any argument Allergan made to the Examiner as to what art is or is not the closest cannot be material because it would not have changed the Examiner's decision to allow the claims. *Therasense*, 649 F.3d at 1291-92 (noting that materiality means that "the PTO would not have allowed a claim had it been aware of the undisclosed prior art").

Sandoz's allegations as to intent merely repeat its flawed materiality assertions and then state that "the only plausible reason such omissions and misrepresentations were made was because they were part of an active plan to deceive the PTO." (*See, e.g.*, Dkt. 73, Counterclaim ¶ 210.) Sandoz's bald conclusion, which relies on its "materiality" assertions and lacks any factual allegation to prove intent, is insufficient as a matter of law. *See Eagle View*, 2018 WL 1522708, at *8 (dismissing inequitable conduct affirmative defense based on insufficient intent allegations where defendants made the "tautological argument" that "the omission to disclose Kennedy prosecution specifics by itself necessarily indicates deception").

b. Sandoz's Allegations Concerning the Schiffman Declaration in Prosecution Lack Materiality, Plausibility, and Intent (Basis 2)

In basis 2, Sandoz alleges that Allergan misrepresented the incidence of central nervous system adverse events in an affidavit submitted by Dr. Schiffman and failed to disclose he was an Allergan employee, and that, but for these supposed misrepresentations, the Examiner would not have allowed the patents. (Dkt. 73, Counterclaim ¶¶ 211, 213-216, 239.) As an initial matter, Allegan corrected that omission in the very next response, well before the '149 patent issued, informing the Examiner that Allergan "overlooked mentioning in the previous action that

the expert who signed the rule 132 affidavit is an employee of the assignee." (*Id.* at ¶ 216; Ex. D, '149 File History, May 16, 2005 Amendment at 3.) Because Allergan provided the Examiner with the information about Dr. Schiffman's employment before that claims were allowed, its initial omission cannot be material. *See Young*, 492 F.3d at 1349 ("[W]e cannot agree that there was inequitable conduct resulting from the 'failure to disclose material information' when that information was disclosed to the PTO in time for the examiner to consider it.").

Moreover, it is not plausible that anything related to the Schiffman declaration would have changed the Examiner's mind about allowing the claims because the Examiner, in fact, did not rely on that declaration in allowing the claims, stating instead that he "***cannot*** consider the applicant's submitted data as the overcoming evidences for the obviousness rejection." (Ex. D, '149 File History, Office Action dated December 16, 2004, p. 9 (emphasis added)). And during prosecution of the '463 patent, where Dr. Schiffman's declaration was submitted again, the Examiner—the same person as in the '149 patent—again did not allow the claims based on the declaration. Rather, the Examiner did not allow the claims until Allergan submitted a declaration showing the commercial success of Combigan®. (Ex. E, *see* '463 File History, Notice of Allowability at 2 ("Claims 26-31 are allowable over the prior art of the record in light of the commercial success of the claimed products (Declaration filed 09/26/2007).")

For similar reasons, it is not plausible that Mr. Johnson, Mr. Wurst, or anyone else involved in the prosecution acted with the intent to deceive in relation to the Schiffman declaration. Instead, their actions—such as correcting the failure to identify Dr. Schiffman as an employee in his declaration—are evidence of just the opposite.

c. Sandoz's Allegations Based on Dr. Duh's Report Lack Materiality, Intent, and Plausibility Because they Are Contrary to Dr. Duh's Own Conclusions (Basis 3)

Sandoz's third basis for its inequitable conduct allegations—that Allergan withheld the expert report of Dr. Mei Sheng Duh dated May 27, 2016 from the second litigation—similarly fails the materiality and plausibility requirements as a matter of law. According to Sandoz, Allergan should have provided Dr. Duh's report to the Examiner because Dr. Duh's report "shows that Combigan® is not as effective as thrice daily brimonidine administration." (Dkt. 73, Counterclaim ¶ 250.) As it did with its "closest prior art" allegations, Sandoz again improperly treats its own attorney argument as a "material fact" that Allergan should have disclosed to the Examiner. *See Artemi*, 2013 WL 6860734, *4. Sandoz's allegations do not show a material misrepresentation of fact; instead, they are merely Sandoz's view of the data.

Sandoz's allegations are contradicted by the very document they would have had the Patent Office consider. Unlike Sandoz, Dr. Duh concludes that "[b]oth glaucoma and ocular hypertension patient groups demonstrate ***consistent and similar IOP efficacy results*** in the comparison between Combination and Brimonidine." (Dkt. 86-10, Walsh Decl., Ex. I at ¶ 31.1.) ("Combination" refers to Combigan®.) She goes on to explain that "Combination is statistically significantly superior to Brimonidine at all time points except for hour 9. At hour 9, there were no statistically significant differences in the mean IOP reductions from baseline between Combination and Brimonidine." (*Id.*) Thus, any allegation that Dr. Duh's report shows Combigan® is not as effective as brimonidine three times daily is a factual misrepresentation—but one made by Sandoz, not Allergan, Dr. Duh, or any Allergan prosecuting attorney or agent.

Indeed, while Sandoz trumpets Dr. Duh's report in its counterclaim, it was not actually presented by either party at trial in the second litigation over Sandoz's skinny label product. Dr. Duh did not testify on behalf of Allergan, and Sandoz did not present testimony from her, despite

having taken her deposition for an entire day. Allegations of materiality require more than simply pointing to a document that was not cited—they require that the patent would not have issued but for the withholding of the document. *See U.S. Water Servs., Inc. v. Novozymes A/S*, 843 F.3d 1345, 1353 (Fed. Cir. 2016). Sandoz's allegations of materiality with respect to Dr. Duh's report do not even reach the threadbare.

Finally, it is not plausible that Mr. Siddiqi intended to deceive the Patent Office in not disclosing Dr. Duh's expert report. The far more reasonable interpretation, which is consistent with his testimony in this case, is that he was simply not aware of the report.

d. Sandoz's Allegations that Allergan Did Not Properly Disclose or Discuss Certain Data to the PTO Are Neither Plausible Nor Material (Bases 1, 2, 4, 5, 7, 8)

Sandoz's allegations that, but for Allergan's failure to disclose particular pieces of data (particularly the 12T study (basis 7), the FDA's Combigan® Medical Review (bases 5, 8), the Alphagan® Final Report (bases 1, 2, 4, 6), and the 23T clinical study (basis 4)), the claims would not have issued fare no better as to materiality, intent, or plausibility. As the public record of the prior litigations reveals, Sandoz has previously identified and advanced arguments on these very same references in previous litigations, and the courts nonetheless upheld the validity of the patents. *Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d. 974, 977 (E.D. Tex. Aug. 22, 2011); (Ex. A (*Allergan Sales*, slip op.) ¶¶ 105, 162-165. Because none of these references are invalidating art, and the courts have found unexpected results after seeing the data in all of them, there is no but-for materiality as a matter of law. *See Therasense*, 649 F.3d at 1291-92 (noting that materiality means that "the PTO would not have allowed a claim had it been aware of the undisclosed prior art"); *see also Mentor Graphics Corp. v. EVE-USA, Inc.*, 13 F. Supp. 3d 1116, 1124 (D. Or. 2014) (finding no materiality where PTO had not instituted inter partes review

based on prior art with disclosures similar to the allegedly material art that the patentee purportedly withheld).

And it is not conceivable—let alone plausible—that prosecuting attorneys Johnson, Wurst, and Siddiqi intended to deceive the Patent Office by advancing arguments related to the therapeutic effects of Combigan® that four courts have already agreed with. (*See supra* Section II.) The far more reasonable inference is that these prosecutors simply advanced arguments that ultimately would either be accepted in Court in the future (Dr. Johnson and Mr. Wurst) or had already been accepted in Court (Mr. Wurst and Mr. Siddiqi).

e. Sandoz's Assertions that Allergan Failed to Disclose the David Reference Are Neither Material Nor Plausible (Basis 6)

With respect to basis 6, it is not plausible that Allergan's alleged omission of the David reference was material to the patentability of any of the Allergan patent family claims.

Perhaps most tellingly, despite a significant incentive to invalidate the very patents it now claims were obtained through inequitable conduct, Sandoz never bothered to cite David in any of the prior litigations between the parties, through multiple sets of invalidity contentions, interrogatory responses, expert reports, and § 282 prior art disclosures encompassing hundreds of references. That alone should demonstrate that lack of plausibility of Sandoz's allegations on the materiality of David here.

But Sandoz did cite and rely on the articles discussed in David in the prior cases, and Allergan, in turn, cited those articles to the Patent Office. David is a review paper comparing the safety and efficacy of brimonidine 0.2% with timolol 0.5%, both administered twice daily, based on data collected at years three and four of long-term studies. (Dkt. 73, Counterclaims ¶ 188; Ex. F (David).) Because it is a review paper, David discusses the results set forth in other articles—i.e., it does not reflect independent research. (*Id.*) Of the fifteen articles cited in the

portion of David that Sandoz relies on, Sandoz offered thirteen of them to the Court as potential invalidating references in the prior litigations. (Exs. G-H (Section 282 notices).) The only two not cited were references numbers 8 and 9, which contain information not referred to by Sandoz in its counterclaims and which are irrelevant to the issues Sandoz raises. (*Id.*) There is nothing in David that is any different than the record in the prior litigations over which Sandoz lost.

Moreover, eleven of the fifteen references were cited on the face of one or more of the previously-litigated patents. (*See, e.g.*, Dkt. 57-4, Ex. Y, '425 patent (citing references 1-8, 12, 13, and 15 of the David article).) *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.3d 1435, (Fed. Cir. 2006) ("A reference that is simply cumulative to other references does not meet the threshold of materiality that is predicate to a holding of inequitable conduct."); *see also St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, No. 2-CV-441-RGA, 2014 WL 2622240, at *3 (D. Del. June 11, 2014) (requiring defendant to "plead facts explaining why the omitted references are not cumulative of other prior art reviewed during prosecution"). The David reference is not material, let alone "but-for" material, and Sandoz's allegations on David are implausible.

3. Sandoz's Allegations of "Burying" References Are Not Material or Plausible (Basis 8)

Finally, Sandoz's allegations of "burying" in basis 8 highlight the internal inconsistency in Sandoz's positions. After alleging in bases 1, 2, and 4-7 that Allergan failed to disclose material references, Sandoz changes course and alleges that Allergan committed inequitable conduct by burying the examiner in too much prior art. Sandoz cannot have it both ways, and its inconsistent allegations fail to meet the materiality or plausibility requirements. And intent to deceive is a completely unreasonable inference. Instead, the far more reasonable inference is that Allergan's attorneys were submitting the prior art identified by Sandoz and its co-defendants in the ongoing litigations to meet their duty of candor to the Patent Office.

C. Sandoz Fails to Allege Sham or a Series of Shams (Counterclaims 16-18)

1. Sandoz Cannot Meet the High Burden to Strip Allergan of Its Noerr-Pennington Immunity Regardless of Which Standard Applies

Sandoz must satisfy a high burden to plead that Allergan filed sham litigations. Allergan, like all patent owners, has the lawful right to enforce patents and exclude competitors. Under the "*Noerr-Pennington* doctrine," the First Amendment shields conduct petitioning the government, including the courts, from antitrust liability. *See, e.g., In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 147 (3d Cir. 2017) ("A plaintiff claiming that a lawsuit is, by its very existence, anticompetitive and unlawful faces an uphill battle.").

To strip a party filing a patent infringement lawsuit of *Noerr-Pennington* immunity, Sandoz must show, at a minimum, that a lawsuit was objectively baseless. *PRE*, 508 U.S. at 60–61. When considering a large "series of legal proceedings," the Third Circuit has applied a more flexible but similar approach to determine if a significant number of the lawsuits were objectively baseless—the so-called "series test." *See Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 179–80 (3d Cir. 2015) ("[T]he question is not whether any one [lawsuit] has merit . . . but whether they are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.").[13]

[13] As a threshold matter, the series test should not apply. Allergan filed suit according to the Hatch-Waxman Act. The Third Circuit has never applied the series test in this context, recognizing that "[t]he serial petitioning charge is particularly inapt because [these] actions [are] consistent with the design and intent of Hatch-Waxman." *Wellbutrin*, 868 F.3d at 157. Additionally, the number of lawsuits is too few to qualify as a "series." In *Hanover*, the Third Circuit acknowledged that four lawsuits are not even always enough to qualify as a series. 806 F.3d at 181 ("[W]e do not… find that four sham litigations will always support use of [the series test]."). Despite Sandoz's attempts to splice this case into numerous lawsuits, it boils down to two prior litigations or three at most. Allergan filed its first lawsuit in 2009. After winning, Allergan brought additional claims based upon newly issued patents in 2012 and in 2015, which were ultimately consolidated. Allergan filed this current lawsuit in 2017. The Federal Circuit has found that three lawsuits "are not 'simultaneous and voluminous' and do not implicate a test

Regardless of which test applies, Sandoz fails to plausibly allege sham litigation. Under *PRE*, a sham litigation claim fails if a lawsuit is not objectively baseless. 508 U.S. at 60–61. Under the series test, the Third Circuit examines the "win-loss percentage," and there can be no sham "[i]f more than an insignificant number of filings have objective merit." *Hanover*, 806 F.3d at 181. Thus, both standards at their core assess whether the patent infringement lawsuits at issue have ***objective*** merit. And if a litigant wins or could reasonably believe that it "ha[s] some chance of winning," then a lawsuit (or multiple lawsuits) has objective merit. *PRE*, 508 U.S. at 65. Because Sandoz does not—and cannot—plausibly allege that ***any lawsuit filed by Allergan*** was objectively baseless, Sandoz's sham litigation claims fail under either standard.

2. Sandoz Fails to Plausibly Allege Objectively Baseless Lawsuits

Allergan had a reasonable basis for filing each lawsuit. Issued patents are presumptively valid, and "that presumption takes away any need for a plaintiff to prove his patent is valid to bring a claim." *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1929 (2015). In fact, "it will be a rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation." *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014).

Additionally, Allergan filed each lawsuit based upon technical acts of infringement under the Hatch-Waxman Act. The Third Circuit recognizes that "[t]he already high hurdle for stating an antitrust claim for anticompetitive litigation is higher still in the context of an ANDA case[.]" *Wellbutrin*, 868 F.3d at 149, 157. Allergan filed its first suit in response to notice of Sandoz's ANDA, which automatically qualified as an act of infringement. *See AstraZeneca AB v. Mylan Labs., Inc.*, No. 00–6749, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) ("Mylan gave

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for 'a whole series of legal proceedings.'" *ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1291–92 (Fed. Cir. 2010). Thus, the *PRE* test should apply in this context.

Astra an objectively reasonable basis to sue: Mylan provided Astra notice of its Paragraph IV certification."). After Allergan won, Sandoz amended its ANDA, prompting Allergan to file the next consolidated suit. Allergan was "objectively reasonable in acting on that technical act of infringement, and that alone is therefore a sufficient basis" for filing suit. *Wellbutrin*, 868 F.3d at 149. Any alleged "litigiousness [is thus] a product of Hatch-Waxman" rather than Allergan. *Kaiser Found. Health Plan, Inc. v. Abbott Labs, Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009).

a. Allergan Won its First Lawsuit

Next, Sandoz's claim that Allergan's first lawsuit was objectively baseless fails as a matter of law. The Supreme Court established that "[a] winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." *PRE*, 508 U.S. at 60 n.5. Allergan prevailed in the district court on validity and infringement. Additionally, Sandoz ***stipulated to infringement*** of the asserted claims of the patents-in-suit leaving invalidity as its only defense before trial. (Dkt. 86-10 Ex. B at 8:20-9:5.) Upon appeal, the Federal Circuit affirmed the district court's finding that one patent was valid and infringed by Sandoz. Sandoz thus cannot plausibly argue that this winning lawsuit lacked objective merit.

b. Allergan Won in the District Court in its Consolidated Second Lawsuit, Which Was, At a Minimum, a Hard-Fought Case

Sandoz cannot show that the second consolidated lawsuit was objectively baseless because Allergan succeeded on the merits at the district court—"an important factor to be considered under the sham inquiry." *Boulware v. State of Nevada, Dep't of Human Res.*, 960 F.2d 793, 798 (9th Cir. 1992). After extensive litigation on appeal, the Federal Circuit ultimately affirmed the validity of one patent but reversed the finding of infringement. However, Allergan's success in the district court is highly persuasive that the case had objective merit. Courts routinely hold that non-frivolous lawsuits cannot give rise to liability even if unsuccessful

or if the patents are found invalid. *See, e.g.*, *AstraZeneca*, 2010 WL 2079722, at *4 (granting 12(b)(6) dismissal in Hatch-Waxman context: "This court may not infer automatically that Astra's infringement action against Mylan was objectively baseless just because Astra lost at trial.").[14] In fact, this Court has refused to find sham litigation simply when the defendant survived summary judgment. *See Syncsort Inc. v. Innovative Routines Int'l Inc.*, 2008 WL 1925304, at *18 (D.N.J. Apr. 30, 2008) ("That this Court is not granting summary judgment . . . on all of Syncsort's claims demonstrates that Syncsort had a ***reasonable belief*** that there was a chance that its claims would be upheld upon adjudication.") (emphasis added). Here, Allergan prevailed with the district court finding three patents valid and one patent infringed. That factor alone should put to rest any notion that this consolidated lawsuit was a "sham." At worst, the case was "hard-fought and close," and such an "outcome hardly bespeaks baseless litigation." *AstraZeneca*, 2010 WL 2079722, at *4.

c. The Present Litigation Has Yet to Be Adjudicated

The present litigation is pending based upon newly issued patents, which are presumed valid and enforceable. 35 U.S.C. § 282. Moreover, Allergan has an objectively reasonable basis to enforce these patents given that the USPTO issued them after Allergan revised its claims to specifically address the "claiming problem" identified by the Federal Circuit in the prior case. If Allergan prevails, as it did in its first lawsuit and initially in its second consolidated lawsuit, then Sandoz's sham litigation claims fail under either *PRE* or the series test. Even if the case is hard-

[14] *See also Ervin Equip. Inc. v. Wabash Nat'l Corp.*, No. 15- CV-104, 2017 WL 416304, at *3 (N.D. Ind. Jan. 31, 2017) (same: "While I dismissed two of the three claims in the original complaint and denied the motion for preliminary injunction, those rulings were not slam dunks."); *cf. Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH*, 524 F.3d 1254, 1261-64 (Fed. Cir. 2008) (infringement-related communications were not objectively baseless even where ALJ found infringement in action for only one of ten patents); *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1305 (Fed. Cir. 2004) (infringement claim was not objectively baseless even though voluntarily dismissed).

fought but unsuccessful, the result is the same. *See supra* Section D.1.c.

In sum, given the presumption of validity for Allergan's patents, the design of the Hatch-Waxman Act, Allergan's first winning lawsuit, Allergan's initial success in its second consolidated lawsuit, and the current pending action based upon newly issued patents, Sandoz has not— and cannot—plausibly allege that any of Allergan's patent infringements lawsuit were objectively baseless. Thus, there can be no sham litigation under either standard. Sandoz's monopolization claims (Counterclaims 16-18) should be dismissed accordingly.[15]

3. If Sandoz's Antitrust Counterclaims Are Not Dismissed, at a Minimum, the Court Should Stay Those Claims (Counterclaim 15-18)

Alternatively, the Court should exercise its discretion to bifurcate and stay Sandoz's antitrust counterclaims until the validity of the patents is adjudicated. *See Landis v. N. Am. Co.*, 299 U.S. 248, 254–55 (1936). Consistent with Rule 42(b), the Federal Circuit recognized over 30 years ago the "standard practice" to "separat[e] for trial patent issues and those raised in an antitrust counterclaim," and courts in this District have adhered to this practice. *In re Innotron Diagnostics*, 800 F.2d 1077, 1084 (Fed. Cir. 1986).[16] Sandoz has in fact tried this tactic before only to have its antitrust counterclaims bifurcated with discovery stayed by this very Court. *See Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762, 2009 WL 10678670 (D.N.J. Apr. 9,

[15] Sandoz's monopolization "scheme" claim (Counterclaim 16) fails in turn. Stripped of its rhetoric, the heart of the alleged scheme is that Allergan filed sham litigations. (*See* Dkt. 73, Counterclaims ¶ 73.) Given that Sandoz fails to plausibly allege any sham, however, there is no independent basis for an antitrust claim. Sandoz's scheme claim should be dismissed. The same reasoning applies to Sandoz's state law monopolization claim (Counterclaim 18). Because the New Jersey Antitrust Act is interpreted in harmony with the Sherman Act, Sandoz's state law claim fails. *See Prime Aid. Pharm. Corp. v. Humana Inc.*, No.16–2104, 2017 WL 2889677, at *3 n.2 (D.N.J. Mar. 2, 2017) ("Because this Court has concluded that Plaintiff has insufficiently pled its federal antitrust claims, this Court will dismiss Plaintiff's state law antitrust claim.").

[16] *See, e.g., Otsuka Pharm. Co. v. Apotex Corp.*, No. 14-8074, 2016 WL 6246801, at *5 (D.N.J. Aug. 26, 2016); *Abraxis Bioscience, Inc. v. Navinta LLC*, No. 07–1251, 2008 WL 2967034, at *8 (D.N.J. July 31, 2008); *Warner Lambert Co. v. Purepac Pham. Co.*, No. 98–2749, 2000 WL 34213890, at *11 (D.N.J. Dec. 22, 2000).

2009). The same result is warranted here.

First, judicial efficiency favors a stay. The "resolution of the patent infringement issues may render [defendant's] antitrust Counterclaim moot, thereby serving the interests of judicial economy." *Otsuka*, 118 F. Supp. 3d at 653. If Allergan defeats the inequitable conduct claims, then the *Walker Process* claim fails as a matter of law. If Allergan prevails (or has a reasonable chance of prevailing) then there will be no basis at all for the other antitrust counterclaims. Allergan will therefore be entitled to seek an injunction, and Sandoz will have no damages.

Second, burdensome, unrelated antitrust discovery favors a stay. Sandoz must show all of the elements of a Section 2 claim and establish antitrust standing**.** They "raise[] complex issues potentially requiring discovery well beyond what is relevant to patent infringement and invalidity." *Orthophoenix, LLC v. Dfine, Inc.*, No. 13–1003, 2015 WL 1938702, at *1 (D. Del. Apr. 28, 2015).[17] These antitrust issues will require unrelated expensive fact, expert, and third party discovery that would consume resources and tax the Court with inevitable disputes.

Third, injecting antitrust issues into a patent case may result in jury confusion and potentially unfair bias, to the extent the antitrust and patent issues are tried together to a jury. Allergan's claims implicate three patents, as well as facts related to brimonidine, timolol, and the treatment of ocular hypertension. To "add antitrust issues to patent issues would pose a difficult task for even the most astute of juries." *Ricoh Co. v. Katun Corp.*, No. 03- CV-2612, 2005 WL 6965048, at *1 (D.N.J. July 14, 2005). Also, antitrust counterclaims "may unfairly sway the jury against … an accused monopolizer." *Hunter Douglas, Inc. v. Comfortex Corp.*, 44 F. Supp. 2d

[17] For example, the "relevant market" will be a hotly contested issue. Sandoz alleges a narrow product market limited to "Combigan® and its generic alternatives," (Dkt. 73, Answer ¶ 457), but the Third Circuit has dismissed pharmaceutical cases with similar market definitions. *See Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 437 (3d Cir. 2016).

145, 154 (N.D.N.Y. 1999).

Finally, Sandoz will not be prejudiced by a stay given its own delay. Sandoz could have brought these antitrust counterclaims years ago. Having made that strategic decision, Sandoz cannot now claim to be prejudiced by a stay. Additionally, Sandoz delayed asserting these claims in this very action. Fact discovery is scheduled to close on June 8—less than three weeks away—and the extensive discovery required for key antitrust-specific issues could not possibly be completed in such a short time. (Dkt. 34.)

V. CONCLUSION

For the reasons above, Allergan respectfully requests that the Court dismiss Sandoz's inequitable conduct and antitrust counterclaims (counterclaims 7-18) and strike Sandoz's tenth affirmative defense.

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Respectfully submitted,

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